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EXAMINER				
CHEN, STACY BROWN				
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/784,305  
Filing Date: February 24, 2004  
Appellant(s): FULTON ET AL.

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Lee Cheng  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed July 10, 2007 appealing from the Office action mailed August 30, 2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Appellant's brief presents arguments relating to an objection to the specification under 35 U.S.C. § 132 for introducing new matter. This issue relates to petitionable subject matter under 37 CFR 1.181 and not to appealable subject matter. See MPEP § 1002 and § 1201.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claim is drawn to a fusion protein comprising a mA116 single-chain variable fragment antibody (scFv Ab) fused with streptavidin-binding peptide (SBP). The fusion protein sequence is encoded by SEQ ID NO: 1, and the encoded sequence is SEQ ID NO: 2. The claim's recitation of "a mA116 scFv Ab" is meant to encompass a genus of antibodies. The specification as originally filed and original claim 10 refer to "mA116 scFv" as if it were a single antibody in and of itself. An exemplary portion of the specification and original claim 10 are reproduced below:

Page 6, first paragraph states:

In order to further explore the potentiality of mA116 scFv Ab as an immunodiagnostic reagent for detecting VEE, the present inventors successfully fused a streptavidin-binding peptide (SBP) to mA116 scFv Ab by DNA recombinant technique. This confers a streptavidin-binding function on the mA116 scFv Ab and therefore obviates the need for conventional chemical biotinylation.

Original claim 10:

The SBP tagged recombinant scFv Ab fusion protein of claim 4, wherein said scFv Ab is mA116 scFv Ab.

Based on the specification as originally filed, and original claim 10, the reference to mA116 was in the context of a single antibody. However, claim 10 as amended refers to "a" mA116, indicating that mA116 itself is a genus of antibodies. This interpretation of the claim language is evidenced by appellant's attempt to introduce the other mA116 antibodies in the post-filing amendment of January 23, 2006 which has not been entered. Therefore, there is no support in the specification for a reference to "a" mA116 scFv because there is only one mA116 scFv according to the original disclosure.

#### **(10) Response to Argument**

Appellant's arguments have been carefully considered but fail to persuade. Appellant asserts that the subject matter of claim 10 is described in the specification and claims in sufficient detail via words and structures to establish that the inventor had possession of the claimed invention. In particular, appellant notes that scFv Ab is defined as a mA116 scFv Ab which according to the description in the *Background of the Invention* section of the specification is a well-characterized scFv Ab against VEE based on previously known publications. Appellant argues that given the examples of mA116 scFv Abs and their respective Deposit Accession Numbers provided by the Appellants, and the teachings of the structures of the claimed fusion protein in the incorporated references, specification and claims, appellant has clearly established possession of the claimed invention

In response to appellant's arguments, the specification does not disclose that mA116 scFv is a genus of antibodies, or any of the identifying information relating to the members of the mA116 genus. Appellant looks to the Alvi *et al.* reference (*Viral Immunology*, 2003, 16:213-222) for support of A116-6, mA116-4, mA116-6, mA116-14, mA116-15, and mA116-16, which

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was incorporated by reference (see specification, page 18, lines 1 and 2). The incorporation by reference of Alvi *et al.* is not proper and the amendment to the specification that would add the information described in the Alvi *et al.* reference has not been entered. (The Alvi *et al.* reference discloses all of the scFvs except mA116-6.) Without that information about the other antibodies, the specification does not disclose the multiple A116 scFvs that constitute the genus of mA116 scFv.

Appellant also argues that the amendment to claim 10 was to put the claim in better form under U.S. practice by introducing the proper article, "a" before the newly introduced element of "mA116 scFv Ab". In response, the Office acknowledges the reason for the amendment. The amendment also reveals that appellant intends to refer to more than one mA116 scFv Ab, and that any of the mA116 scFv Abs are intended to be encompassed and claimed. This embodiment is not supported by the specification as originally filed. Therefore, the rejection is maintained for reasons of record.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Stacy B. Chen/  
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Conferees:

/Bruce Campell/

Art Unit: 1643

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